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Section 5
5 Fr Single Lumen (SL) PowerGroshong™ PICC Catheter
510(k) Summary

5.1 General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 7136
Fax Number:	(801) 595-5425
Contact Person:	Lynn M. Kirchoff
Date of Preparation:	December 27, 2006
Registration Number:	1720496
Additional Registration Numbers:	
C.R. Bard:	2212754

5.2 Subject Device Information

Device Name:	5 Fr Single Lumen (SL) PowerGroshong™ PICC Catheter
Trade Name:	5 Fr Single Lumen (SL) **PowerGroshong™** PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	80 LJS – Percutaneous, Implanted, Long-Term Intravascular Catheter 21 CFR 880.5970– Class II
Classification Panel:	General Hospital

5.3 Predicate Device Information

Device Name(s):	5 Fr Dual Lumen (DL) Groshong® nXt PICC Catheter 6 Fr Triple Lumen (TL) PowerPICC® Catheter
Trade Name(s):	**Groshong® nXt, PowerPICC®**
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	80 LJS – Percutaneous, Implanted, Long-Term Intravascular Catheter 21 CFR 880.5970– Class II
Classification Panel:	General Hospital

Predicate Device Name	510(k)	Clearance Date
5 Fr DL **Groshong®** nXt PICC Catheter	K023374	12/18/2002
6 Fr TL **PowerPICC®** Catheter	K053501	1/13/2006

5.4 Intended Use

The intended use of the 5 Fr SL PowerGroshong is the same as the intended use of the predicate devices.

The **PowerGroshong™** PICC is intended for short or long-term peripheral access to the central venous system for intravenous therapy, and blood sampling.

5.5 Indications for Use

The Indications for Use for the 5 Fr SL **PowerGroshong™** PICC Catheter is as follows:

The **PowerGroshong™** PICC is intended for short or long-term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. The maximum recommended infusion rate is 4 ml/sec for power injection of contrast media.

5.6 Device Description

The **PowerGroshong™** PICC catheters are valved, long-term peripheral access catheters. The catheters are made of silicone material to which a blue and purple colorant have been added. Blue colorants were added to the catheter materials to allow the users to identify the catheter as a Groshong distally valved catheter. Purple colorants were added to the catheter materials to provide the catheter with an appearance that allows the end user to differentiate Bard's power injectable catheters from other manufacturers' power injectable catheters. The **PowerGroshong™** PICC catheters are available in 5 Fr single lumen catheter configuration. The catheters are packaged in basic and full with microintroducer kits that incorporate kit components designed to meet the needs of the respective placer.

5.7 Technological Comparison to Predicate Devices

The technological characteristics of the 5 Fr SL **PowerGroshong™** PICC are substantially equivalent to those of the predicate devices in terms of intended use, application, user population, basic design, performance, labeling, packaging and sterilization method.

5.8 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?
Yes.

Does the new device have the same indication statement and intended use as the predicate?
Yes. The intended use and indications for use are a combination of the indications from the predicate Groshong® nXt and PowerPICC® catheters 510(k) K023374 and K053501.

Does the new device have the same technological characteristics, e.g. design, materials, etc.?
Not in all regards. The principles of operation and basic design are the same as the predicate devices. The main difference is the addition of the power injection indication to a valved catheter.

Could the new characteristics affect safety or effectiveness?
Yes. The design changes may affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?
No. Safety and effectiveness questions are the same as for the predicate devices.

Do accepted scientific methods exist for assessing effects of the new characteristics?
Yes. Testing was performed to assess the new characteristics and was based on the following applicable standards and FDA guidance document:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
- *BS/EN/ISO 10555-1: 1997, Sterile, single-use intravascular catheters, Part 1. General requirements*

- *BS/EN/ISO 10555-1: 1997, Sterile, single-use intravascular catheters, Part 1. General requirements*
- *ISO 10555-1:1995, Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 1:1999*
- *BS/EN/ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *ISO 594-2: 1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings*
- *ASTM F640-79 (reapproved 2000), Standard Test Methods for Radiopacity of Plastics for Medical Use*
- *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- *AAMI/ANSI/ISO 10993-1:2003, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*

Are performance data available to assess effects of new characteristics?
Yes. Bench testing was based on the above referenced guidance document and standards. All test results confirm that the subject device is substantially equivalent to the predicate devices.

5.9 Conclusion

The 5 Fr SL **PowerGroshong™** PICC met all the performance criteria of the tests performed and, based on FDA's decision tree, is substantially equivalent to its predicate devices, the 5 Fr DL **Groshong®** nXt PICC and the 6 Fr TL **PowerPICC®** Catheter covered by: K023374 and K053501 respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bard Access Systems, Incorporated
Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

APR - 4 2007

Re: K063848
Trade/Device Name: 5 Fr SL PowerGroshong™ PICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: March 1, 2007
Received: March 2, 2007

Dear Ms. Kirchoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K063848

Device Name: 5 Fr SL **PowerGroshong™** PICC Catheter

Indications for Use:

The **PowerGroshong™** PICC is intended for short or long-term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. The maximum recommended infusion rate is 4 ml/sec for power injection of contrast media.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K063848